IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: BUDEPRION XL MARKETING & SALES LITIGATION	:	**MDL No. 2107**
THIS DOCUMENT APPLIES TO: ALL ACTIONS	:	**09-md-2107**

MEMORANDUM

Schiller, J. **July 2, 2012**

And so the parties in this nationwide putative class action lawsuit involving individuals who took a generic antidepressant manufactured and distributed by Defendants have resolved their dispute. On February 1, 2012, the Court granted preliminary approval of the settlement. The parties now seek final approval of the settlement, including reasonable attorneys' fees, costs, and incentive awards for certain Plaintiffs. The Court conducted a fairness hearing on May 25, 2012. For the reasons that follow, the Court certifies the settlement class, approves the settlement, and awards attorneys' fees and costs to Class counsel and incentive awards to certain named Plaintiffs. Thus, this multidistrict litigation comes to a close.

I. BACKGROUND

A. Facts[1]

Bupropion Hydrochloride ("Bupropion") is the active ingredient in the prescription anti-depressant Wellbutrin and several generic antidepressants. (Admin. Class Action Compl. ¶¶ 11-12.)

[1] These facts are largely taken from the Court's May 26, 2010 Memorandum addressing Defendants' motion to dismiss.

By 2007, Buproprion was the fourth-most prescribed antidepressant in this country, with over 20 million retail prescriptions written annually. (*Id.* ¶ 13.) Its side effects include headaches, migraines, agitation, tremors, nervousness, dizziness, decreased memory, insomnia, abdominal pain, nausea, diarrhea, vomiting, chest pains, and seizures. (*Id.* ¶ 20.)

GlaxoSmithKline ("Glaxo") first brought Bupropion to the market in the late 1980s under the name Wellbutrin. (*Id.* ¶ 21.) It was originally available only in an immediate-release formulation, Wellbutrin IR, that the patient was required to take three times per day. (*Id.* ¶ 22.) It used a matrix release mechanism and was metabolized in the upper gastrointestinal tract. (*Id.*) The concentration of Bupropion in the blood peaked two hours after taking Wellbutrin IR. (*Id.* ¶ 23.) The initial sale of Wellbutrin IR, however, was delayed due to the possibility of serious side effects. (*Id.* ¶ 24.)

In 1996, Glaxo introduced Wellbutrin SR, a sustained-release formulation, which also used a matrix release mechanism; concentrations of Buproprion in the blood peaked three hours after taking Wellbutrin SR. (*Id.* ¶¶ 25-26.) Wellbutrin SR users often took two 150 mg pills per day. (*Id.* ¶ 26.) This iteration of the drug was prone to "dose dumping," meaning the drug was absorbed more quickly when the pill was taken with food. (*Id.* ¶ 28.) Glaxo, as well as the generic makers of Wellbutrin SR, disclosed the possibility of dose dumping on their labels, though they considered it clinically insignificant. (*Id.* ¶¶ 28-29.) The Food & Drug Administration ("FDA") did not require a New Drug Application ("NDA") for this formulation; instead, Glaxo was permitted to rely on the data submitted along with the immediate-release formulation. (*Id.* ¶ 25.)

In 2003, Glaxo released Wellbutrin XL, an extended-release formulation that only needed to be taken once per day. (*Id.* ¶ 30.) Wellbutrin XL employed a membrane-release technology, meaning that "the drug was not released through a dissolving pill, but seeped at a controlled rate

through a membrane that actually passed through the entire GI tract intact." (*Id.* ¶ 31.) This release mechanism solved the dose dumping problem, and Glaxo updated its label accordingly. (*Id.* ¶ 32.) Concentrations of Buproprion in the blood peaked five hours after taking Wellbutrin XL. (*Id.*) Additionally, the total amount of Buproprion released was only minimally affected by food and alcohol consumption. (*Id.*) Users of Wellbutrin XL received a steady amount of the medication, which is vital for a once-a-day pill. (*Id.* ¶ 33.) The membrane-release technology was patented, and thus generic drug manufacturers had to devise an extended-release formulation that did not infringe upon the patent. (*Id.* ¶ 34.) Generic drug companies such as Watson Pharmaceuticals and Anchen Pharmaceuticals developed a similar membrane technology, but Defendant Impax Laboratories, Inc. ("Impax") did not. (*Id.* ¶¶ 35-36.)

Impax makes a 150 mg generic product called "bupropion hydrochloride XL," which is distributed by Global Pharmaceuticals, an Impax subsidiary. (*Id.* ¶ 50.) Impax also makes a 300 mg generic drug, Budeprion XL, which is distributed by Defendant Teva Pharmaceuticals ("Teva"). (*Id.* ¶ 49.) The generic versions of Wellbutrin XL involved in this litigation entered the market in late 2006 or early 2007. (*Id.* ¶ 41.) These generics use a matrix technology rather than a membrane-release technology and rely on the size of the pill to control the release of the medication. (*Id.*) The generics subject to this litigation achieve peak concentrations in two hours, versus five hours for Wellbutrin XL and generic versions produced by Anchen and Watson. (*Id.* ¶ 43.) The matrix technology caused Defendants' pills to break apart more quickly than the name brand drugs and metabolize in the upper GI tract. (*Id.* ¶ 44.) Thus, the amount and rate of the active chemical released into the body from Defendants' drugs depended upon factors like food and alcohol consumption, other medications, and other GI issues. (*Id.* ¶ 44.) Users of Wellbutrin XL, on the other

hand, attain the benefits of their medication without these concerns. (*Id.*)

Plaintiffs do not dispute the FDA's finding of bioequivalence, which was necessary to approve the generic drugs before they could be marketed. Instead, Plaintiffs claim that post-approval, Defendants became aware that the differences between Wellbutrin and their products were material, and thus they had a duty to disclose this information. (*Id.* ¶ 48.) Specifically, Plaintiffs say the more rapid release of Defendants' drugs renders them less effective in treating depression and more dangerous than products using a membrane-release technology. (*Id.* ¶ 52.) After Defendants' products arrived on the market, complaints poured in from patients who claimed that the generic drug they were taking was not as effective as Wellbutrin XL, and they were experiencing adverse side effects. (*Id.* ¶¶ 54-56.) Those patients who switched back to Wellbutrin XL or a non-Impax generic drug immediately improved. (*Id.* ¶ 57.) Although Defendants were made aware of the problems with their drugs, they failed to disclose this information or warn patients and doctors about the differences between the medications. (*Id.* ¶ 59.) In fact, to protect their market share, Defendants continued to misrepresent that the release profile of their products was identical to those of the name brand product. (*Id.* ¶¶ 60-62.) Furthermore, during sealed patent litigation involving the delivery method of Defendants' drugs, Defendants touted the differences between their method of delivery and that used in Wellbutrin XL. (*Id.* ¶ 63.) Additionally, studies showed that Budeprion XL released 34% of its Bupropion within the first hour, compared to only 8% for Wellbutrin XL (300 mg). (*Id.* ¶ 64.) And within two hours of ingestion, Budeprion XL released between 25 percent and 50 percent of its Bupropion, compared with less than 20 percent for Wellbutrin XL. (*Id.* ¶ 66.) In April 2008, under pressure from consumers, non-profit watchdogs, and the medical community, the FDA issued a report explaining some of the differences between Wellbutrin XL and Defendants' generic product;

however, the FDA made no determination as to whether Defendants' warnings were adequate. (*Id.* ¶ 69.)

According to the Complaint, Defendants have made the following omissions and misrepresentations, among others: (1) failure to disclose that the Bupropion contained in Budeprion XL reaches its peak concentration in the bloodstream in just two hours and instead insisting that maximum levels are only reached after five hours; (2) failure to disclose that taking Defendants' products with food increases the amount of the drug eventually released into the body, thereby causing adverse events; (3) failure to disclose that the 300 mg generic drug was never tested for bioequivalence with Wellbutrin XL; (4) failure to disclose the existence of tests indicating that the dissolution of Defendants' products varies significantly from Wellbutrin XL; (5) failure to disclose numerous complaints of adverse side effects and decreased efficacy suffered by persons who switched from Wellbutrin XL to Defendants' products; (6) failure to disclose that their products have a different physiological and therapeutic effect than Wellbutrin XL; (7) failure to disclose that Defendants' products employ an inferior release technology; and (8) misrepresenting that their product work the same as Wellbutrin XL. (*Id.* ¶ 71.) Defendants also failed to inform those taking their drugs that they needed to be closely monitored. (*Id.* ¶¶ 72-75.) Defendants kept all of this information secret in an effort to protect their market share. (*Id.* ¶ 76.) According to the Complaint, if Plaintiffs knew the truth about Defendants' generic products, they would not have purchased those products. (*Id.* ¶ 142.) As a result, they suffered injury and lost money because they paid for an unsatisfactory product. (*Id.* ¶ 153.)

B. History of the Litigation

This litigation developed from the numerous complaints filed in both federal and state courts

throughout this country. It began in this District, on June 22, 2009, with the filing of *Rosenfeld v. Teva Pharmaceuticals, Inc.*, Civ. A. No. 09-2811. Similar cases were filed in, or removed to, federal courts in the Central District of California, the Middle District of Florida, the Eastern District of Louisiana, the Eastern District of North Carolina, the Northern District of Texas, the Southern District of Ohio, the Southern District of Alabama, the Northern District of Oklahoma, and the Western District of Washington. In all of these cases, Plaintiffs sought to represent themselves and a class of individuals who had taken Defendants' generic version of Wellbutrin and whose conditions had worsened after switching to the drug. Both Plaintiffs and Defendants agreed that the cases should go to the United States Judicial Panel on Multidistrict Litigation (the "MDL Panel") and be consolidated for pretrial purposes, although the parties disputed to which district the cases should be transferred. On December 2, 2009, the MDL panel issued its decision and, pursuant to 28 U.S.C. § 1407, transferred the cases to this District.

Although this litigation began as a number of distinct cases brought throughout the country seeking to apply various state laws, Plaintiffs employed a different strategy once the MDL Panel transferred the litigation here. Thus, on March 1, 2010, class representatives Micki Sackler and Andrew Richards filed an Administrative Class Action Complaint. As stated in the Administrative Class Action Complaint, "[t]his lawsuit seeks to apply California's statutory business standards to a California drug manufacturer (Impax) and its distribution partner (Teva) for uniform national conduct emanating from California. Defendants engage in nationwide market activity, providing the same label with every Impax Product that omits material information. A national solution makes sense." (*Id.* ¶¶ 99-100.)

The Administrative Class Action Complaint stated that the Class consisted of:

> All persons or entities in the United States who purchased, paid-for (in whole or in part), Bupropion Hydrochloride XL (150 mg) and/or Budeprion XL (300 mg) manufactured by Impax.
>
> Excluded from the Classes are Defendants, any parent, subsidiary or affiliate of Defendants, and their officers, directors, and employees, who are or have been employed by Defendants, and any judicial officer who may preside over this action.

(*Id*. ¶ 19.) Plaintiffs sued under California's Unfair Competition Law based on the omissions and misrepresentations surrounding Defendants' products. Plaintiffs allege that Defendants engaged in a pattern of unfair business practices that has harmed consumers, physicians, pharmacies, and insurance companies. They further allege that Defendants' actions have harmed competitors in that they allowed Defendants to unfairly seize market share. They also brought a claim under the California Consumer Legal Remedies Act for Defendants' failure to disclose the differences between their products and Wellbutrin XL, including the decreased efficacy and increased risks of Defendants' products. Defendants filed a motion to dismiss on March 26, 2010, arguing federal law preempted Plaintiffs' claims, and following the denial of Defendants' motion, Defendants answered the Administrative Class Action Complaint and discovery commenced in earnest. Plaintiffs moved for class certification on January 31, 2011. On June 23, 2011, the Supreme Court decided *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), which revived the preemption argument on which Defendants relied in their motion to dismiss. In September 2011, the parties filed cross-motions for summary judgment based on the preemption issue. On November 8, 2011, the parties participated in an 11-hour mediation session with the Hon. Diane M. Welsh (Ret.). With her continued help, the parties agreed to settle their dispute.

On February 1, 2012, following a hearing, the Court conditionally certified the class and

granted preliminary approval to the settlement agreement. In accordance with the Court's directive, the parties sent out notice of the settlement to the class. Class members were afforded the opportunity to object to the settlement. The Court conducted a fairness hearing on May 25, 2012, in which the Court heard from one of the three objectors. The parties have fully briefed the issues that must be decided to grant final approval of the settlement.

C. Settlement Terms

The "Settlement Class" comprises:

> All individuals in the United States who, from 2006 to the present, purchased and/or paid-for (in whole or in part), for personal use and not for resale, Buproprion Hydrochloride XL (150 mg) and/or Budeprion XL (300-mg) manufactured by Impax. Excluded from the class are Defendants, any parent, subsidiary or affiliate of Defendants, and their officers, directors, and employees, who are or have been employed by Defendants, and any judicial officer who may preside over this action.

(Settlement Agreement ¶ 3.)

Pursuant to the settlement agreement, Defendants agree to do the following:

a. Permanently change the prescribing insert for 300 mg Budeprion XL ("BP XL") to remove certain references to the trade name Budeprion XL;

b. Permanently change the disclosure regarding United States Pharmacopeia testing from "pending" to "meets USP Dissolution Test 6 ";

c. Refrain from selling the 500 count bottle of BP XL unless done in accordance with CBE-0 dated December 15, 2010 and submitted to the FDA;

d. Implement monitoring in 2012 and 2013 to ensure that Standard Operating Procedures are followed regarding investigations of consumer complaints relating to BP XL;

e. Implement monitoring in 2012 and 2013 to ensure compliance with Corrective Action/Preventative Action relating to BP XL;

f. Designate a senior quality and compliance officer for 2012 and 2013 who will oversee the quality of BP XL. This individual must report to one or more

> members of the board of directors about the quality and current Good Manufacturing Practice compliance. The Secretary of the Board must certify to class counsel Allan Kanner that the report was made; and
>
> g. Post on the Impax website any future voluntary recalls related to BP XL.

(*Id*. ¶ 7.)

The named Plaintiffs and the Settlement Class agreed to release Defendants from "any and all statutory or common-law claims for equitable or injunctive relief that have been or could have been brought in the Included Actions, including but not limited to any claim for restitution asserted in the Consolidated Administrative Class Action Complaint or any other statutory or common-law claim for restitution related to their use of BP XL." (*Id*. ¶ 12.) However, members of the class did not release any personal injury claims against Defendants. (*Id*.)

D. Notice

Class counsel submitted an affidavit from Jeffrey Dahl, a "nationally-recognized expert with over 19 years of experience in class action settlement administration." (Pls.' Mot. for Final Approval of Class Action Settlement Ex. 1 [Dahl Aff.] ¶ 1.) Dahl explained the administration of the proposed Class action settlement of this litigation. Pursuant to the Class Action Fairness Act, notice of the proposed settlement was sent to the appropriate state officials, including the District of Columbia and the Commonwealth of Puerto Rico. (*Id*. ¶¶ 4-5.) Additionally, Court-approved published notice appeared in the *New York Times* on February 12 and 26, 2012 and in *USA Today* on February 20 and March 5, 2012. (*Id*. ¶ 7.) A toll-free settlement helpline was also established. (*Id*. ¶ 8.) Finally, a settlement website was set up, which included settlement information, frequently asked questions, a list of important dates and deadlines, and links to relevant documents from the litigation. (*Id*. ¶¶ 11-12.)

II. DISCUSSION

A. Class Certification

1. Rule 23(a)

A party seeking class certification must demonstrate: (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class. Fed. R. Civ. P. 23(a)(1)-(4). These prerequisites are commonly referred to as numerosity, commonality, typicality, and adequacy of representation. *See Behrend v. Comcast Corp.*, 655 F.3d 182, 189 (3d Cir. 2011). If the dictates of Rule 23(a) are satisfied, the proposed class must satisfy at least one of the three requirements set forth in Rule 23(b). *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2548 (2011). The proposed class here relies on Rule 23(b)(2), which applies when "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief is appropriate respecting the class as a whole."

The Court here is faced with a settlement-only class. The fact that a settlement is in place is relevant to the issue of class certification and thus may be considered by the court. *In re Pet Food Prods. Liab. Litig.*, 629 F.3d 333, 341 (3d Cir. 2010). While some of the requirements of Rule 23 demand heightened scrutiny in the settlement context, a court need not determine whether a case, if tried, would present intractable management problems, since the settlement negates the need for a trial. *Id*.

a. Numerosity

"No minimum number of plaintiffs is required to maintain a suit as a class action, but

generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met." *Stewart v. Abraham*, 275 F.3d 220, 226-27 (3d Cir. 2001). Clearly, the numerosity requirement is met here. Although the exact size of the class is unknown, Class counsel estimates the total number of class members to be as many as 2,235,000, though at a minimum the "proposed class consists of hundreds of thousands of persons in the United States who paid for the Impax product subject to this litigation." (Pls.' Mot. for Prelim. Approval of Proposed Class Action Settlement Ex. 2 [Kanner Prelim. Approval Decl.] ¶ 40.) The numerosity requirement is easily met here.

b. Commonality

The commonality requirement of Rule 23(a)(2) is met if the named plaintiffs share "at least one question of fact or law with the grievances of the prospective class." *Baby Neal v. Casey*, 43 F.3d 48, 56 (3d Cir. 1994). To satisfy this requirement, the named plaintiffs must show that the class members have suffered the same injury; that is, a "common contention . . . capable of classwide resolution." *Dukes*, 131 S. Ct. at 2551.

Defendants are alleged to have engaged in the same course of conduct as to all members of the Class. This litigation—and the resulting settlement—involve Defendants' business practices. Those practices were felt by all Class members in an identical manner and the legal propriety of those practices remains unvaried across the Class. The common contention here is readily capable of classwide resolution. Therefore, the Court finds that the commonality prong is satisfied.

c. Typicality

The typicality requirement demands that the claims or defenses of the representative parties are typical of the claims and defenses of the class; the interests of the class and the class

representatives should mesh "so that the latter will work to benefit the entire class through the pursuit of their own goals." *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 182-83 (3d Cir. 2001). This requirement is satisfied so long as "the claims of the named plaintiffs and putative class members involve the same conduct by the defendant . . . regardless of factual differences." *Johnston v. HBO Film Mgmt., Inc.*, 265 F.3d 178, 184 (3d Cir. 2001).

All of the representative individuals are alleged to have suffered the same injuries as the remaining Class members. The representative Plaintiffs all took Defendants' products to treat their depression but their symptoms instead worsened. Had they known that the differences in Defendants' products rendered them useless as anti-depressants, Plaintiffs would not have purchased Defendants' medication. Defendants failed to disclose important information to consumers, in violation of California consumer protection laws. From the beginning of this litigation, Defendants have raised factual questions as to whether certain Class members read the labels on Defendants' drugs prior to ingesting them, whether other factors might have led to a worsening of symptoms in certain Class members, and whether certain Class members continued taking Defendants' drug because it remained effective for them. Nonetheless, the story remained the same for all Class members: Defendants' misrepresentations and omissions led to users taking a less efficacious and potentially dangerous medicine unbeknownst to them. The typicality prong is established here.

d. Adequacy of representation

Rule 23(a) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). The adequacy component of Rule 23 involves two

inquiries. First, is counsel qualified and experienced to represent the class?[2] *See In re Gen. Motors Corp. Pick-up Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768, 800 (3d Cir. 1995). Second, do the named plaintiffs have interests antagonistic to those of the class? *See New Directions Treatment Servs. v. City of Reading*, 490 F.3d 293, 313 (3d Cir. 2007). This second requirement aims "to uncover conflicts of interests between named parties and the class they seek to represent." *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 532 (3d Cir. 2004). "Class representatives must be part of the class and possess the same interest and suffer the same injury as the class members." *Pet Food*, 629 F.3d at 343 (internal quotations marks omitted). The court must be satisfied that the named plaintiffs have the ability and the incentive to represent the claims of the class vigorously. *Larson v. AT&T Mobility LLC*, App. A. Nos. 10-1285/1477/1486/1578, 2012 U.S. App. LEXIS 13292, at *64-65 (3d Cir. June 29, 2012). Additionally, whether class counsel is qualified to represent the class requires the court to consider: (1) the work counsel has done in identifying or investigating potential claims in the action; (2) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action; (3) counsel's knowledge of the applicable law; and (4) the resources that counsel will commit to representing the class. Fed. R. Civ. P. 23(g)(1)(A)(I) - (iv); *In re Cmty. Bank of N. Va.*, 622 F.3d 275, 291-92, 305 (3d Cir. 2005). In the context of a settlement class, a court must assure itself that class counsel has adequate experience, vigorously prosecuted the action, and acted at arm's length from the defendant. *Cmty. Bank*, 622 F.3d at 304-05.

Jaquelyn Anderson objects to certification of the Class in part because the underlying claims

[2] "Although questions concerning the adequacy of class counsel were traditionally analyzed under the aegis of the adequate representation requirement of Rule 23(a)(4) of the Federal Rules of Civil Procedure, those questions have, since 2003, been governed by Rule 23(g)." *Sheinberg v. Sorensen*, 606 F.3d 130, 132 (3d Cir. 2010).

in this litigation are based upon different states' laws, necessitating separate class representatives for states with dissimilar laws. (Anderson Objection at 5-6.) This objection fails to recognize that Plaintiffs sought to bring this litigation as a nationwide class action applying California law. Thus, it is incorrect to suggest that different states' laws would need to be applied. Additionally, such a concern is greatly alleviated by the fact that this is a settlement class, and therefore the threat of "intractable management problems" that might arise should this litigation go to trial are not relevant here. *See Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 303-04 (3d Cir. 2011) (noting previous decision that variations in state consumer protection laws were irrelevant because "a settlement would eliminate the principal burden of establishing the elements of liability under disparate laws"). The Court finds no conflict present or any reason to suggest that the named Plaintiffs were unable or unwilling to vigorously advocate on behalf of the entire class. Furthermore, as the settlement agreement includes only relief shared by all Class members identically, nothing in the record suggests to the Court that the named Plaintiffs acted in conflict with the Class or failed to vigorously pursue the claims of all Class members.

Anderson also reports that because the underlying litigation class could not be certified, the class representatives negotiated from a "disarmed" position when discussing settlement. (Anderson Objection at 6.) This objection runs contrary to the viewpoint of Diane Welsh, the former United States Magistrate Judge who guided the parties through an eleven-hour mediation. (Pls.' Mot. for Award of Reasonable Att'ys' Fees, Costs and Serv. Awards [Pls.' Mot. for Att'ys' Fees] Ex. 2 [Welsh Aff.] ¶¶ 11-12.) "Throughout the entire mediation process, it was clear to [Welsh] that each of the parties were represented by experienced and competent counsel, willing, if necessary, to litigate the matter to conclusion." (*Id.* ¶ 14.) Welsh was confident that the parties were represented

by "zealous advocates." (*Id.* ¶ 16.) The Court rejects the contention that Class counsel was disarmed. Though their case was not without its difficulties, Class counsel continuously demonstrated a willingness to advance legal arguments on behalf of their clients.

Nobody has voiced an objection to Class counsel's experience and ability to represent this Class. Class counsel performed ably and with great aplomb in the face of a difficult case against Defendants' experienced and talented lawyers. The experience of Class counsel is set forth in the declaration of Allan Kanner. (Pls.' Mot. for Att'ys' Fees Ex. 1 [Kanner Fees Decl.] ¶¶ 16-24.) Counsel for the class fought hard for their clients, and the Court is convinced that this portion of the adequacy of representation prong is easily met.

2. Rule 23(b)

In addition to the four prerequisites set forth in Rule 23(a), the class must also meet the dictates of Rule 23(b). Here, the Class seeks certification under Rule 23(b)(2), which authorizes class actions if "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief . . . is appropriate respecting the class as a whole." Actions seeking injunctive relief normally satisfy this requirement. *See also Baby Neal*, 43 F.3d at 58 (noting that 23(b)(2) requirement "is almost automatically satisfied in actions primarily seeking injunctive relief"). To certify a class under this provision, the relief sought should benefit the entire class. *Sullivan*, 667 F.3d at 317-18. "[T]he putative class must demonstrate that the interests of the class members are so like those of the individual representatives that injustice will not result from their being bound by such judgment in the subsequent application of principles of *res judicata*." *Hassine v. Jeffes*, 846 F.2d 169, 179 (3d Cir. 1988). This rule applies if a single injunction would provide relief to each class member. *Dukes*, 131 S. Ct. at 2557. Conversely, it does not permit class

certification when each individual class member would be entitled to a different injunction against the defendant or if each class member would be entitled to an individualized award of monetary damages. *Id*.

One of the three objections received by the Court argues that certification under Rule 23(b)(2) is not permissible here because Plaintiffs sought individualized monetary damages in the nature of restitution. (Anderson Objection at 1-2.) Defendants made a similar argument at the class certification stage. (*See* Defs.' Opp'n at 26-27.)

This Class is properly certified under Rule 23(b)(2). The Court offers two responses to the objection that certification is inappropriate. First, the fact that monetary damages may have been awarded does not foreclose certifying a Rule 23(b)(2) class. Second, the Court is certifying a Rule 23(b)(2) settlement class receiving only injunctive relief.

a. Money damages does not foreclose certification

While Rule 23(b)(2) is not the appropriate vehicle for a class seeking an individualized award of monetary damages, the Supreme Court in *Dukes* left open "whether there are any forms of incidental monetary relief that are consistent with the interpretation of Rule 23(b)(2) . . . and that comply with the Due Process Clause." *Gates v. Rohm & Hass Co.*, 655 F.3d 255, 263 (3d Cir. 2011). When plaintiffs request injunctive and declaratory relief and damages, the propriety of certification depends upon the predominant form of relief sought. *Id*. The Third Circuit has not addressed the appropriate test for district courts to use in determining whether the relief sought is primarily injunctive or declaratory. *See Hohider v. United Parcel Serv., Inc.*, 574 F.3d 169, 198 (3d Cir. 2009) ("[W]e have not yet spoken on how the predominance of monetary relief in the Rule 23(b)(2) context should be measured and our sister circuits are split on that question.") A number

of courts in this District have used the "incidental damages" test articulated by the Fifth Circuit Court of Appeals in *Allison v. Citgo Petroleum Co.*, 151 F.3d 402 (5th Cir. 1998). *See, e.g.*, *Clarke v. Lane*, 267 F.R.D. 180, 198-99 (E.D. Pa. 2010); *Allen v. Holiday Universal*, 249 F.R.D. 166, 189 (E.D. Pa. 2008); *Gaston v. Exelon Corp.*, 247 F.R.D. 75, 87 (E.D. Pa. 2007); *Pichler v. UNITE*, 228 F.R.D. 230, 256 (E.D. Pa. 2005); *see also Barabin v. Aramark Corp.*, App. A. No. 02-8057, 2003 WL 355417, at *1-2 (3d Cir. Jan. 24, 2003) (finding no error when district court applied test set forth in *Allison*). Incidental damages are those that "flow directly from liability to the class *as a whole* on the claims forming the basis of the injunctive or declaratory relief." *Allison*, 151 F.3d at 415. Such incidental damages should ideally arise automatically upon a finding of liability to the class and should also be capable of computation though objective standards and not dependent on the unique circumstances of individual class members. *Id*. "Liability for incidental damages should not require additional hearings to resolve the disparate merits of each individual's case; it should neither introduce new and substantial legal or factual issues, nor entail complex individualized determinations." *Id*.

It is a close question whether this class action, as filed, satisfies the mandates of Rule 23(b)(2). The objection that individual Class members sought monetary damages has merit. Plaintiffs sought restitution and injunctive relief under the California Consumer Legal Remedies Act, as well as a $5,000 statutory penalty per class member. The California Consumer Legal Remedies Act permits the recovery of actual damages, restitution of property, and injunctive relief. Cal. Civ. Code § 1780. The Class also brought claims under California's Unfair Competition Law, which allows prevailing plaintiffs to recover restitution, and obtain injunctive relief. *See Korea Supply Co. v. Lockheed Martin Corp.*, 63 P.3d 937, 943 (Cal. 2003) ("A UCL action is equitable in nature;

damages cannot be recovered."). But labeling restitution as an equitable remedy, as Plaintiffs argue here, does not make it so. Whether restitution qualifies as an equitable remedy depends on the basis of the claims and the nature of the remedies sought; it is equitable in nature when ordered in a case in equity. *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 213 (2002) (noting that restitution is both a remedy at law and in equity).

Plaintiffs sought injunctive relief that would benefit the entire Class identically. Additionally, Plaintiffs sought statutory damages, which would avoid an individualized calculation of damages. Plaintiffs also proposed a complicated mechanism whereby restitution damages could be calculated for the entire Class. The Court concludes that the request of statutory damages does not foreclose certifying a Rule 23(b)(2) settlement class.

b. This is a settlement only class

Because the Court is certifying a Rule 23(b)(2) settlement class receiving only injunctive relief, it is freed from some of the problems that might arise if this litigation were to be tried, including calculating damages. As the Court is reviewing a settlement in which only injunctive relief is to be awarded, no individual damages calculation is necessary. The fact that damages might have been difficult to ascertain or may have presented an obstacle to certification of a litigation class is no objection to certification of a settlement class that obviates the need for any individualized damages calculation. "The concern for manageability that is a central tenet in the certification of a litigation class is removed from the equation." *Sullivan*, 667 F.3d at 302-03.

The objection to certification under Rule 23(b)(2) here would tie the Court's hands by forcing it to ignore the fluid nature of litigation. The objectors view the question of class certification as frozen in time based on the allegations in the class action complaint. This is unrealistic and runs

counter to the principle that the law favors settlement of class actions.[3] *See Gen. Motors*, 55 F.3d at 784 ("The law favors settlement, particularly in class actions and other complex cases where substantial judicial resources can be conserved by avoiding formal litigation."). The parties are free to agree to anything in reference to the subject matter of the litigation. *See Sullivan*, 667 F.3d at 317.

The Court will not subvert a settlement negotiated at arm's length because a litigation class may have presented difficult issues for certification at an earlier stage in the proceedings. The language of Rule 23(b)(2) is clear: such a class may be certified if the party opposing the class has acted in a way applicable generally to the class so that final injunctive relief is appropriate respecting the class as whole. Having satisfied that standard, no more is required. Thus, the Court concludes that the Class has met its burden to demonstrate that it has satisfied the dictates of Rule 23(b)(2).

B. Settlement

1. Girsh Factors

"The claims, issues, or defenses of a certified class may be settled, voluntarily dismissed, or compromised only with the court's approval." Fed. R. Civ. P. 23(e). Because the settlement would bind class members, this Court may only approve the settlement upon a finding that it is "fair, reasonable, and adequate." Fed. R. Civ. P. 23(e)(2). The Third Circuit has described the district court's role under Rule 23(e) as a fiduciary that must protect the unnamed class members from unjust or unfair settlements. *Pet Food Prods.*, 629 F.3d at 349-50. When, as here, class certification is sought in conjunction with settlement approval, district courts must "apply an even more rigorous,

[3] The Court is aware that a district court must find that a class meets the requirement of Rule 23, regardless of whether the Court is asked to certify a litigation class or a settlement class. *Prudential*, 148 F.3d at 308. Nonetheless, the Court may take the proposed settlement into account when deciding the issue of certification. *Id.*

heightened standard . . . designed to ensure that class counsel has demonstrated sustained advocacy throughout the course of the proceedings and has protected the interests of all class members." *Id*. at 350. Nonetheless, there is an overriding public interest in settling class action cases that warrants an especially strong presumption is favor of voluntary settlements in class actions. *Id*. at 351.

The settling parties must demonstrate—and the Court must make findings as to—the nine factors laid out in *Girsh v. Jepson*, 521 F.2d 153, 157 (3d Cir. 1975). The *Girsh* factors are: (1) the complexity, expense and likely duration of the litigation; (2) the reaction of the class to the settlement; (3) the stage of the proceedings and the amount of discovery completed; (4) the risks of establishing liability; (5) the risks of establishing damages; (6) the risks of maintaining the class action through the trial; (7) the ability of the defendants to withstand a greater judgment; (8) the range of reasonableness of the settlement fund in light of the best possible recovery; and (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation. *Id*. at 157. Since the announcement of the *Girsh* factors, the Third Circuit has also advanced additional inquiries that courts may find useful when reviewing the settlement agreement of a class action:

> [T]he maturity of the underlying substantive issues, as measured by experience in adjudicating individual actions, the development of scientific knowledge, the extent of discovery on the merits, and other factors that bear on the ability to assess the probable outcome of a trial on the merits of liability and individual damages; the existence and probable outcome of claims by other classes and subclasses; the comparison between the results achieved by the settlement for individual class or subclass members and the results achieved—or likely to be achieved—for other claimants; whether class or subclass members are accorded the right to opt out of the settlement; whether any provisions for attorneys' fees are reasonable; and whether the procedure for processing individual claims under the settlement is fair and reasonable.

In re Prudential Ins. Co. Am. Sales Practices Litig. Agent Actions, 148 F.3d 283, 323 (3d Cir. 1998).

Although the burden rests with the settling parties to demonstrate the *Girsh* factors favor settlement, an initial presumption may apply in cases, such as this, in which: "(1) the settlement negotiations occurred at arm's length; (2) there was sufficient discovery; (3) the proponents of the settlement are experienced in similar litigation; and (4) only a small fraction of the class objected." *Sullivan*, 667 F.3d at 320 n.54.

a. Complexity, expense, and likely duration of the litigation

The first *Girsh* factor looks at the time and money likely necessary if the litigation continued. *Id*. at 320. Settlement here will save a small fortune in time and money. The legal issue of preemption has been prominent in this case and Defendants' pending summary judgment motion relies heavily on that doctrine. Adding to the paperwork, Plaintiffs filed their own summary judgment motion. Additionally, the parties have briefed the issue of class certification and have battled over which state or states' laws must apply to this litigation. There are also *Daubert* motions pending. The parties even dispute whether certain pleadings should be unsealed. A trial in this action would consume considerable resources and cost a massive amount. Similarly, an appeal (or appeals) would likely be forthcoming once the Court ruled on the issues of class certification and summary judgment.

Furthermore, the legal issues presented do not lend themselves to easy answers. And, if this case proceeded to trial, a jury would be faced with complicated factual questions related to the business practices of Defendants, federal generic drug regulations, the chemical composition of prescription medication, as well as the bodily reactions of class members to that medication. A jury would see a veritable parade of fact and expert witnesses aimed at describing the world of generic drugs, and it would go down the rabbit hole of Defendants' marketing, research, and development

for the drugs at issue. Although the parties have traveled a long way in terms of discovery and motion practice, there is still a long way to go. This factor weighs greatly in favor of settlement.

b. Reaction of the class to the settlement

Based upon the number of objectors and their arguments, does the class support the settlement? *Prudential*, 148 F.3d at 318. Silence from the class generally indicates agreement, although "the practical realities of class actions ha[ve] led a number of courts to be considerably more cautious about inferring support from a small number of objectors to a sophisticated settlement." *Gen. Motors*, 55 F.3d at 812.

The Court has received three objections. Jaquelyn Anderson raises a number of concerns about the settlement. She posits that the settlement should create a presumption of unfairness because the Class members receive no money, yet Defendants receive a release of the claims against them. (Anderson Objection at 8-11.) She also claims that people who have stopped using the drugs at issue receive no benefit at all from the agreed-upon injunctive relief. (*Id*. at 9.) And the injunctive relief is illusory because it only applies to future sales of the drugs at issue. (*Id*. at 11-13.)

Anderson also takes issue with the award of attorneys' fees in this case. She argues the fee requested by class counsel is grossly disproportional to the benefits, if any, obtained for the class, because "there are virtually no tangible benefits obtained for the class in this settlement. Thus, only a minimal award, if any, is justified. And certainly not a seven figure fee." (*Id*. at 15.) Anderson also argues that Class counsel were obligated to state exactly how much money they were requesting in fees, and having failed to do so, their notice to the Class was deficient. (*Id*. at 15-16.) Finally, Anderson finds fault with the incentive awards because they will go to Class members other than Sackler and Richards. (*Id*. at 16.)

The Texas State Attorney General also filed an objection to the settlement, complaining that it is akin to a coupon settlement with the attorneys receiving all of the proceeds. (Tex. State Att'y Gen. Objection at 2.) The State Attorney General also complains that Defendants are merely agreeing to take actions they have already undertaken. (*Id*. at 1.) The State Attorney General notes that despite the Supreme Court's ruling in *Mensing*, Defendants are willing to pay $4.5 million to end this case, yet none of the money goes to any of the Class members, and Class members are required to relinquish their right to sue for restitution. The objection closes with the suggestion that "any future terms of settlement should include either some form of monetary relief for class members or a release of injunctive claims only." (*Id*. at 3.)

The third objection comes from Class member Michael Carroll. He objects to the settlement and seeks $5,000 for each Class member to be paid from each Defendant. (Carroll Objection.) His objection is general in nature and fails to cite any law or touch on what he deems unfair about the settlement.

Three objectors out of a class that numbers potentially over two million people is a small fraction; such a minuscule number of objectors weighs in favor of settlement. *See McDonough v. Toys "R" Us, Inc.*, Civ. A. Nos. 06-242, 09-6151, 2011 WL 6425116, at *3-4 (E.D. Pa. Dec. 21, 2011) (concluding that ten objections out of a class of 1,281,636 favored settlement). Although the objections raise some legitimate concerns, ultimately they are without merit. Thus, the number and substance of the objections weighs in favor of settlement.

c. Stage of the proceedings and the amount of discovery completed

The third *Girsh* factor "'captures the degree of case development that class counsel had accomplished prior to settlement,' and allows the court to 'determine whether counsel had an

adequate appreciation of the merits of the case before negotiating.'" *Sullivan*, 667 F.3d at 321 (quoting *Warfarin*, 391 F.3d at 537). Here, the settlement occurred after discovery, a fact that favors approval. *See Bell Atl. Corp. v. Bolger*, 2 F.3d 1304, 1314 (3d Cir. 1993) ("[P]ost-discovery settlements are more likely to reflect the true value of the claim and be fair.").

Class counsel knew their case, as "Plaintiffs received and reviewed over 200,000 pages of documents produced in discovery." (Kanner Fees Decl. ¶ 7.) Plaintiffs sought and took over sixteen non-expert depositions, defended the ten depositions of the class representatives, took or defended ten expert depositions, and filed briefs and argued motions touching on the procedural and substantive facets of this case. (*Id.* ¶¶ 7-9, 15.) The parties also worked on extensive mediation submissions and engaged in a comprehensive mediation session that addressed the strengths and weaknesses of their parties' positions. (Welsh Decl. ¶¶ 8, 11-12, 18.) The lawyers on both sides, zealously advocating on behalf of their clients, have raised myriad discovery issues to be decided by the Court. The parties have briefed the relevant legal issues and made their arguments regarding liability, damages, preemption, class certification, and experts both to the Court and each other. All of the cards are laid out on the table; no stone was left unturned.

d. Risks of establishing liability

"By evaluating the risks of establishing liability, the district court can examine what the potential rewards (or downside) of litigation might have been had class counsel elected to litigate the claims rather than settle them." *Gen. Motors*, 55 F.3d at 814.

The Court has been involved with this litigation almost from its inception. The Court judges the terms of the settlement from a unique vantage point. As the objectors point out, Plaintiffs appear to be leaving this litigation with much less than they sought when these cases were originally filed.

The Court will spend some time discussing the risks the Class has of achieving any success in this litigation, because this factor plays a critical role in the Court's decision that the settlement is fair, reasonable, and adequate.

(i.) Motion to dismiss

Plaintiffs faced a significant hurdle with respect to establishing liability, and, unfortunately for the Class, the hurdle was placed before them by the Supreme Court. Defendants filed a motion to dismiss the claims of the proposed class, arguing that they were preempted by federal law. This Court disagreed, relying on case law holding that generic drug makers could effectuate generic prescription medication label changes and that federal regulations demanded that generic drug makers revise their labels to warn of clinically significant dangers as soon as reasonable evidence of a causal association between the drug and the danger appeared.

This Court reasoned that its decision was mandated by the Supreme Court's ruling in *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Levine*, the Supreme Court held that it was not impossible for name brand drug manufacturers to comply with both federal law and state tort law in modifying drug labels approved by the FDA. Thus, federal law did not preempt state law failure to warn claims brought against brand name prescription drug makers. Although *Levine* did not address generic drug makers, this Court examined cases that applied *Levine* in that context, including the Fifth Circuit Court of Appeals decision in *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), and the Eighth Circuit Court of Appeals decision in *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). Both of those decisions concluded that preemption did not bar state law claims against generic drug manufacturers. Given the legal landscape, the writing was on the wall: because simultaneous compliance with federal and state law was not impossible and the ultimate responsibility for product

safety rested with the generic drug maker, federal law did not preempt state law tort claims. At this stage of the proceedings, the Class was in an excellent position. Although the Class still faced significant legal and factual obstacles, the Court concluded that the Class stated a claim.

(ii.) Mensing *holding*

The Supreme Court, however, erased the writing on the wall. When the *Demahy* and *Mensing* decisions were appealed, the Supreme Court was faced with two state laws that required that drug makers aware of a danger associated with their product adequately label the product to warn about the danger. The generic drug manufacturers in *Mensing* and *Demahy* allegedly failed to comport with these state law duties. The Court noted that federal regulations permit generic drugs to gain FDA approval "simply by showing equivalence to a reference listed drug that has already been approved by the FDA." *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011). Thus, "brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." *Id*.

The Supreme Court held that after initial FDA approval of a generic drug, the drug manufacturer was foreclosed by federal law from changing its label without FDA approval. This was based on the FDA's reading of the relevant laws and regulations that the warning label of a generic drug must be the same as that of the brand name drug. Thus, a generic drug maker could not unilaterally avail itself of certain processes to strengthen a warning label or warn doctors and patients of additional dangers associated with a generic drug. *Id*. at 2576-77.

The FDA maintained that if a generic drug maker felt that additional warnings were required,

the manufacturer was required to notify the FDA, which would then determine if a label change was necessary, and if so, would work to create a new label for both the brand name and generic drugs. "Generic drug manufacturers that become aware of safety problems must ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug." *Id*. at 2576. The Supreme Court found it unnecessary to decide whether generic drug makers had a duty to request a strengthened label because the Court "ultimately [found] pre-emption even assuming such a duty existed." *Id*. at 2577.

The Supreme Court held that it was impossible for generic drug makers to simultaneously comply with state laws that would require a different, stronger label and federal drug regulations that prevented them from independently changing their safety labels. "It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law." *Id*. at 2577-78. Because the generic drug makers could not comply with both federal law and state law without a federal agency permitting them to do so, federal law preempted state law. The Court thus held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes." *Id*. at 2581.

The Supreme Court in *Mensing* briefly addressed the apparent incongruity between its ruling and the decision in *Levine*, which was issued just two years earlier. The ruling in *Levine* was not contrary to *Mensing* because the federal regulations at issue in *Levine* allowed the company, on its own, to strengthen its label. *Id*. The Supreme Court recognized that from the perspective of the plaintiffs in *Mensing* and *Demahy* its opinion made little sense but pushed the blame for that onto

Congress, which was responsible for the statutory scheme at issue. *Id*. at 2581-82.

(iii.) Conclusion

Of course, the *Mensing* decision produced an absurd outcome. *See id*. at 2592 (Sotomayor, J. dissenting) ("Today's decision leads to so many absurd consequences that I cannot fathom that Congress would have intended to pre-empt state law in these cases."). The ruling stripped consumers of compensation if harmed by inadequate warnings on generic drugs. *Id*. at 2592. The right to file a lawsuit for injuries caused by inadequate warnings now rested on the arbitrary decision of whether a pharmacist used a generic or brand name drug to fill a prescription. *Id*. The ruling also eliminated the state law incentives for generic drug makers to monitor and disclose safety risks because brand name drug makers often leave the market once a generic becomes available. *Id*. at 2592-93. Finally, the ruling also undermined the law that generic and brand name drugs are the same in nearly all respects, which may eventually reduce consumer demand for generic drugs. *Id*. at 2593. The dissent did not interpret federal law to permit generic drug makers "to remain idle when they conclude their labeling is inadequate." *Id*. at 2585.

An individual's ability to sue for damages caused by prescription medication should not depend on whether the drug was a name brand or a generic. If drug manufacturers are legally responsible for their products (like every other maker of a good), generic drug makers should not be immune from liability. The Supreme Court decision renders generic drug makers parrots, free from liability provided they do a competent job copying the label of the name brand drug makers' label. It also rewrites the decision in *Levine* in that a hypothetical or speculative conflict would supplant the previous impossibility standard employed in the preemption context. But this Court is bound to apply the law as interpreted by the Supreme Court. Thus, the Supreme Court's decision in *Mensing*

raised a serious problem for Plaintiffs in this case. Defendants filed a motion for summary judgment, relying on the holding in *Mensing*. In the wake of *Mensing*, numerous courts have thrown out similar cases based on preemption. *See, e.g.*, *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011); *Brinkley v. Pfizer, Inc.*, Civ. A. No. 10-274, 2012 WL 1564945 (W.D. Mo. Apr. 12, 2012); *Metz v. Wyeth, Inc.*, Civ. A. No. 10-2658, 2012 WL 1058870 (M.D. Fla. Mar. 28, 2012); *Bell v. Pliva, Inc.*, Civ. A. No. 10-101, 2012 WL 640742 (E.D. Ark. Feb. 16, 2012); *Moretti v. Mut. Pharm. Co.*, Civ. A. No. 10-896, 2012 WL 465867 (D. Minn. Feb. 13, 2012); *Fullington v. Pliva, Inc.*, Civ. A. No. 10-236, 2011 WL 6153608 (W.D. Ark. Dec. 12, 2011). Refusing to concede the fight, Plaintiffs filed a motion for summary judgment attempting to distinguish *Mensing*. Indeed, some courts faced with a preemption argument post-*Mensing* have nonetheless deemed the case inapplicable to the facts before them or have refused to foreclose recovery based on *Mensing*. *See, e.g.*, *Bartlett v. Mut. Pharm. Co.*, App. A. No. 10-2277, 2012 WL 1522004 (1st Cir. May 2, 2012); *Couick v. Wyeth, Inc.*, Civ. A. No. 09-210, 2012 WL 79670 (W.D.N.C. Feb. 16, 2012); *Brasley-Thrash v. Teva Pharms. USA, Inc.*, Civ. A. No. 10-31, 2012 WL 4025734 (S.D. Ala. Sept. 12, 2011); *Hassett v. Dafoe*, 2012 WL 1512551 (C.C.P. Phila. Mar. 22, 2012). The recency of the *Mensing* decision makes it possible that its holding will ultimately be read narrowly. But there can be no dispute that the *Mensing* decision made it significantly more difficult for the proposed class to establish liability. And the preemption question raised only a threshold issue. Even if the Class emerged victorious on the issue, the Class faced a fierce battle from Defendants on the merits of their claims under California law, or whatever laws the Court ultimately decided applied to their claims, as well as certification of a litigation class. This factor weighs heavily in favor of settlement.

e. Risks of establishing damages

This factor largely overlaps with the risks of establishing liability, which the Court discussed above. Additionally, the issue of calculating restitution relief also presented problems for the Class. And as noted by the Class, "recovery would likely be further decreased by the amounts paid for the prescription by the third party payor insurance companies." (Pls.' Mem. in Supp. of Mot. for Final Approval of Class Action Settlement [Pls.' Final Approval Mem.] at 25.) It was also unclear what injunctive relief the Court would be able to provide the Class should it prevail at trial. For example, it was never clear to this Court that it possessed the legal power or proper scientific acumen to re-write the label for Defendants' products. Furthermore, to the extent Plaintiffs aim to change the label or have the drugs removed from the market, this Court arguably cannot grant such relief "without invading the province of FDA." (Defs.' Br. in Opp'n to Pls.' Mot. for Class Cert. [Defs.' Opp'n] at 26.) Avoiding a trial allows the Court to approve relief it might not have been able to award at trial, while providing Defendants with the certainty gained by avoiding trial. *See Sullivan*, 667 F.3d at 317 ("[T]he District Court here could reasonably approve a mutually agreed-upon stipulation enjoining conduct within the Court's jurisdiction regardless of whether the plaintiffs could have received identical relief in a contested suit."). These additional hurdles on the issue of the relief to be provided in the event the Class won at trial weigh in favor of approving the settlement.

f. Risk of maintaining the class action through the trial

"Under Rule 23, a district court may decertify or modify a class at any time during the litigation if it proves to be unmanageable." *Prudential*, 148 F.3d at 321. Class certification was hotly contested in this litigation. In their response to Plaintiffs' motion for class certification, Defendants identified a plethora of problems that precluded class certification. Defendants argued that the Class

representatives, Sackler and Richards, are not typical because both admitted that they took the generic drug despite knowing of the purported issues related to its efficacy. (Defs.' Br. in Opp'n to Pls.' Mot. for Class Cert. [Defs.' Opp'n] at 19.) Accordingly, both Sackler and Richards would have to defend against charges that they did not reasonably rely upon the alleged omissions. (*Id*.) Furthermore, both Sackler and Richards would be subject to examination on the efficacy of the drug. (*Id*.)

Defendants further contended that Richards and Sackler could not adequately represent the Class. First, Defendants claimed that Richards and Sackler lacked standing to sue under California's Unfair Competition Law and California's Legal Remedies Act because they could not show that the alleged misrepresentations played a substantial role in their decision to purchase the drug. (Defs.' Opp'n at 20-21.) Second, Defendants pointed to a conflict between named Class representatives and putative class members that rendered Richards and Sackler unable to adequately represent the Class:

> The California Class Representatives seek to represent a class of all persons who purchased or paid for BP XL for personal use. Included among those persons are the large number of people who have used BP XL for years, have been satisfied with the drug, and who continue to take it. These individuals would not want a remedy that may effectively stop Impax and Teva from marketing the drug, or that might increase the cost of the drug. Quite the contrary, these individuals would prefer that the drug remain available at the lowest price possible.

(*Id*. at 22.)

And, as discussed earlier, Defendants asserted that the Court cannot certify a Rule 23(b)(2) class. Rule 23(b)(2) allows for class actions when "the party opposing the class has acted or refused to act on grounds generally applicable to the class" and the Class seeks "final injunctive relief or corresponding declaratory relief." Rule 23(b)(2) is inapplicable if the appropriate final relief relates exclusively or predominately to money damages. *Beck v. Maximus, Inc.*, 457 F.3d 291, 301 (3d Cir.

2006).

These potential obstacles presented significant difficulties for class certification, apart from the general concern that a certified class always faces a risk of decertification. A favorable ruling for Plaintiffs on the issue of class certification could have easily been reversed if, in the course of the litigation, management of the Class became too difficult or if factual or legal issues rendered the Court's previous certification unwise. Although the size and variety of issues do not foreclose a settlement class, "there is a significant risk that such a class would create intractable management problems if it were to become a litigation class, and therefore be decertified." *Sullivan*, 667 F.3d at 322.

Given the particularly high risk of decertification or modification here, this favor weighs heavily in favor of approving the settlement.

g. Ability of Defendants to withstand a greater judgment

Defendants are two large pharmaceutical companies. Though the parties have not briefed the question, the Court suspects that the cost of the settlement here to Defendants, at least in terms of money, is negligible. *See id*. at 323 (noting that in any class action against a large corporation, the defendant is likely able to withstand a more substantial judgment). Though the Court is mindful that this factor must be examined against the realistic potential for recovery after a trial, the resources already expended on this litigation lead the Court to believe that Defendants would be able to satisfy a judgment much higher than the Class will recover through the settlement. This factor weighs against settlement.

h. Range of reasonableness of the settlement fund in light of the best possible recovery and in light of all the attendant risks of litigation

These factors examine "whether the settlement represents a good value for a weak case or a poor value for a strong case." *Warfarin*, 391 F.3d at 538. "The reasonableness of a proposed settlement is assessed by comparing the present value of the damages plaintiffs would likely recover if successful [at trial], appropriately discounted for the risk of not prevailing . . . with the amount of the proposed settlement." *Sullivan*, 667 F.3d at 323-24.

This Court has discussed at length the risks faced by the Class if this case did not settle. Following the Supreme Court's decision in *Mensing*, the Class faced the very real possibility of walking away with nothing. Importantly, the settlement does not release personal injury claims that individual Class members may wish to file against Defendants. Thus, those harmed by Defendants' products remain free to vindicate their rights through the courts for any physical or emotional damages they have suffered. Leaving open this possibility for those truly harmed by Defendants' products must be considered a victory for the Class.

According to Anderson, the settlement here is illusory as the Class walks away with nothing. She argues that a number of the changes required by the settlement agreement were already put in place prior to the agreement. (Anderson Objection at 12-13.) She also takes issue with some of the monitoring provisions in the settlement agreement because "[t]here is no requirement that Defendants act on what they find in the monitoring. . . . [A] requirement to monitor does not provide any benefits for how the Defendants must act in response to the result of their monitoring or to the benefit of consumers." (*Id*.)

The Court does not agree with this assessment of the settlement agreement, as the relief

provided is neither meaningless nor illusory. Class members not currently taking Defendants' medications may still be prescribed them in the future. With respect to monitoring, this forces Defendants to take actions previously not required. Though it is ultimately unclear what action, if any, the monitoring will spur, Defendants nonetheless must report to Class counsel. Furthermore, Defendants' failure to comply with the terms of the settlement agreement can lead to sanctions, including a finding that they are in contempt of court. The settlement agreement also makes permanent certain changes Defendants implemented. Absent the settlement agreement, Defendants would face no compulsion to keep these changes in place. Thus, the settlement agreement undeniably works a change in the relationship between the parties, and the relief afforded the Class is not illusory.

In light of *Mensing*, the difficulties in fashioning injunctive relief, and the difficulties in certifying the class, the Court concludes that these last two *Girsh* factors, particularly the reasonableness of the settlement in light of the risks of litigation, weigh in favor of approving the settlement.

i. Prudential *factors*

Although not all of the *Prudential* factors are relevant here, the Court concludes that a number of them weighs in favor of approving the settlement. The underlying substantive issues are mature given the substantial discovery and motion practice that has already occurred. The parties have the bulk of the information required to assess their respective positions. In fact, the parties even have a Supreme Court decision to guide them.

Although there are no opt-out rights for individual Class members because the Class is only receiving injunctive relief, the Court reiterates that the settlement specifically excepts personal injury

claims. (Settlement Agreement ¶ 12 ("For avoidance of doubt, this release by the Settlement Class shall not apply to any claims for personal injury.").) And, of course, the ability to opt-out is irrelevant given the injunctive relief to be provided by Defendants. There is no way for Defendants to take the actions required of them as to some Class members but not others; the injunctive relief benefits all Class members. To the extent the objectors are troubled by Class members' release of their consumer protection claims, this objection addresses a non-existent problem. The only consumer class actions relating to Defendants' drugs are the lawsuits currently before this Court. If individual Class members are releasing a right to sue that none intended to exercise, the Class is not parting with anything of great value.

Finally, as will be discussed more fully below, the Court concludes that the attorneys' fees provided for in the settlement agreement are reasonable. (*See* Settlement Agreement ¶ 13.)

C. Attorneys' Fees

For their efforts, Class counsel seek $4.5 million in attorneys' fees, costs, and incentive awards to certain class representatives. Specifically, Class counsel request $3.2 million in fees, $1.3 million in costs, and $55,000 in incentive awards to nine named Class representatives. (Mem. of Points & Auth. in Supp. of Mot. for Award of Reasonable Att'ys' Fees, Costs & Serv. Awards [Att'ys' Fees Mem.] at 1.) As part of the settlement agreement, Defendants agreed not to oppose Plaintiffs' application for reasonable costs, attorneys' fees, and incentive awards provided the total of Plaintiffs' requests did not exceed $4.5 million dollars. (Settlement Agreement ¶ 13.)

Rule 23(h) of the Federal Rules of Civil Procedure authorizes an award of "reasonable attorney's fees and nontaxable costs that are authorized by law or by the parties' agreement." The court must direct a thorough review of the request for fees. *Gen. Motors*, 55 F.3d at 819. The party

requesting fees must demonstrate the reasonableness of its request and therefore must submit evidence to support its request. *See Hensley v. Eckerhart*, 461 U.S. 424, 433 (1983). The Court must be particularly vigilant in awarding attorneys' fees here because the request for fees exceeds the recovery of the class. *See Reibstein v. Rite Aid Corp.*, 761 F. Supp. 2d 241, 259 (E.D. Pa. 2011).

There are two methods for calculating attorneys' fees in a class action: the percentage-of-recovery method and the lodestar method. *Prudential*, 148 F.3d at 333. The lodestar method is used in statutory-fee-shifting cases. *Id*. (noting that lodestar method "is designed to reward counsel for undertaking socially beneficial litigation in cases where the expected relief has a small enough monetary value that a percentage-of-recovery method would provide inadequate compensation."). The percentage-of-recovery method is preferred when the fee is to be paid from a common fund "because it allows courts to award fees from the fund in a manner that rewards counsel for success and penalizes it for failure." *In re Rite Aid Corp. Sec. Litig.*, 396 F.3d 294, 300 (3d Cir. 2005) (internal quotation marks omitted).

The California Consumer Legal Remedies Act is a fee-shifting statute. Cal. Civ. Code § 1780(e) ("The court shall award costs and attorneys' fees to a prevailing plaintiff in litigation filed pursuant to this section."). California's Unfair Competition Law does not allow for the recovery of attorneys' fees. *City of Santa Monica v. Gabriel*, 186 Cal. App. 4th 882, 889-91 (Cal. Ct. App. 2010). Additionally, in cases such as this one, in which the settlement's terms evade precise evaluation, the lodestar method is preferred. *See Gen. Motors*, 55 F.3d at 821; *see also Prudential*, 148 F.3d at 333 (noting that in addition to statutory fee shifting cases, the lodestar method is appropriate if "the nature of the recovery does not allow the determination of the settlement's value necessary for application of the percentage-of-recovery method"); *Lake v. First Nationwide Bank*,

900 F. Supp. 726, 735 (E.D. Pa. 1995) (using lodestar method because the greatest benefit to the class was a difficult-to-monetize promise to take corrective action.)

The lodestar is calculated by multiplying the number of hours spent by counsel by a reasonable hourly rate. *Id*. at 734. A court determines a reasonable hourly rate by assessing the experience and skill of the prevailing party's attorneys and by looking at the market rates in the relevant community for lawyers of reasonably comparable skill, experience, and reputation. *See Maldonado v. Houstoun*, 256 F.3d 181, 184 (3d Cir. 2001); *see also Student Pub. Interest Research Grp. of N.J., Inc. v. AT & T Bell Labs.*, 842 F.2d 1436, 1450 (3d Cir. 1988). To arrive at a reasonable number of hours worked, the court must excise those hours deemed excessive, redundant, or otherwise unnecessary. *Hensley*, 461 U.S. at 434. Counsel must be sure to properly delegate tasks; the quarterback cannot carry the water bottles. *See Ursic v. Bethlehem Mines*, 719 F.2d 670, 677 (3d Cir. 1983). If counsel sustains its burden to demonstrate the claimed rates and the number of hours worked are reasonable, the lodestar produces a presumptively reasonable attorneys' fee. *Maldonado*, 256 F.3d at 184.

Class counsel detailed the pre-filing investigation, fact and expert discovery, and settlement discussions in an effort to support their request. The investigation into Defendants' product began in April of 2009. (Kanner Fees Decl. ¶ 5.) The first complaint was filed on May 29, 2009, and a number of cases were filed across the country, including the case filed in this District. On December 2, 2009, after the parties battled over where this litigation should proceed, the Judicial Panel on Multidistrict Litigation consolidated for pretrial proceedings the cases filed and transferred them to this Court. Defendants filed a motion to dismiss, which the Court denied. Though Class counsel reviewed thousands of documents prior to briefing on the motion to dismiss, discovery commenced

in earnest after Defendants answered the Complaint. (*Id*. ¶ 7.) "Ultimately, Plaintiffs received and reviewed over 200,000 pages of documents produced in discovery. Plaintiffs likewise produced over 11,000 pages in production." (*Id*.) Additionally, the Court conducted numerous telephone and in-person conferences to address various discovery disputes that arose during the course of the litigation. Plaintiffs took over sixteen non-expert deposition and defended ten depositions of the various Class representatives. (*Id*. ¶¶ 8-9.)

Significant expert discovery was also completed. The Class obtained experts in the areas of pharmacovigilence, product formulation and release technology, consumer preferences, market analysis, and damages calculations. (*Id*. ¶ 10.) "Plaintiffs' experts and consultants expended hundreds of hours conducting research, testing, drafting reports, and being deposed, at a total cost of $654,033." (*Id*. ¶ 15.) Class counsel also deposed each of Defendants' six experts. (*Id*.)

As expected, significant motion practice also occurred. In addition to Defendants' motion to dismiss, the Class filed a motion for class certification and a choice of law brief seeking to have the Court apply California law to the Class's claims. Defendants also filed *Daubert* motions to exclude the Class's experts. Finally, two Supreme Court cases, one involving certification of class actions and another involving preemption, directly affected the claims of the Class and necessitated extensive summary judgment briefing.

On September 26, 2011, the parties retained former United States Magistrate Judge Diane Welsh to mediate their dispute. (Welsh Decl. ¶ 4.) The parties provided Welsh with extensive mediation submissions and engaged in an eleven-hour mediation session. (*Id*. ¶¶ 8, 13.)

Additionally, the request for fees details the experience of the lawyers involved in this litigation. Kanner has more than thirty years of experience in litigating class actions and complex

litigation, including serving as lead counsel for Louisiana in the BP Oil Spill Litigation. (Kanner Fees Decl. ¶ 16.) Along with Conlee Whitely, his firm "has successfully handled national class actions throughout the United States in both state and federal courts." (*Id*. ¶ 17.) Liaison Counsel, Richard Golomb, has over twenty-five years of experience handling cases involving medical negligence, defective products and pharmaceuticals, and personal injury claims. (*Id*. ¶ 18.) His firm, Golomb & Honik, P.C., has also litigated class action complaints throughout the county. (*Id*. ¶ 19.) Gillian Wade, a partner at Milstein Adelman , L.L.P., represents plaintiffs in complex litigation and consumer class actions. (*Id*. ¶ 20.) Her firm specializes in litigating complex cases in a multitude of legal areas, including consumer class actions, civil rights, mass torts, and pharmaceuticals. (*Id*.) Wade's practice includes cases involving violations of California's unfair competition law and the consumer legal remedies act. (*Id*.) The Center for Constitutional Litigation, P.C. specializes in complex litigation on behalf of injured plaintiffs. (*Id*. ¶ 22.) Finally, M. Ryan Casey of Ku & Mussman P.A. has over five years of experience litigating class actions spanning a broad range of practice areas. (*Id*. ¶ 23.)

Class counsel seek hourly rates between $225 to $700 for lead counsel and partners and $200 to $400 for associates. (*Id*. ¶ 37.) According to the information submitted to the Court, over twenty attorneys and six paralegals from fourteen law firms contributed to the 16,903 hours spent on this nationwide class action. (*Id*. ¶¶ 36-37; Pl.'s Mot. for Final Approval of Class Action Settlement Ex. 2 [Billing Record Summary].)

The rates sought are commensurate with rates awarded in other cases. *See Chakejian v. Equifax Info. Servs., LLC*, 275 F.R.D. 201, 216-17 (E.D. Pa. 2011) (accepting rates of $125 to $175 for paralegals and $485 to $700 for partners); *Reibstein*, 761 F. Supp. 2d at 260 (accepting rates of

$650 for partners and $175-$225 for paralegals in a consumer class action litigation) (citing *Serrano v. Sterling Testing Sys., Inc.*, 711 F. Supp. 2d 402, 422 (E.D. Pa. 2010)). The Court also considers reasonable the amount of time spent on this litigation. This litigation spanned years, involved hundreds of thousands of documents, numerous depositions, significant motion practice, and complex legal issues. Fact and expert discovery closed and dispositive motions were filed. It is thus unsurprising that a large number of attorneys was required to spend a significant amount of time on this matter. Calculating the lodestar leads to a result of $6,732,081, a number which the law presumes to be reasonable. Class counsel, mindful of the lack of a monetary recovery for individual Class members, seek $3.2 million in attorneys' fees. Over the objections filed, the Court deems this number a reasonable cut to the lodestar.

According to the objectors, it is unfair that the attorneys are receiving the entirety of the money put forth by Defendants while the vast majority of the individual Class members receive no money. (Anderson Objection at 14-15 ("Defendant was willing to pay at least $4.5 million to settle the class claims, and that money could have gone to benefit class members if class counsel did not grab all of it for themselves."); Tex. State Att'y Gen. Objection at 2 (objecting "because members of the class receive nothing of any monetary value at all, while the attorneys take virtually all the cash that Defendants have put on the table to settle these claims").)

The objections to the size of the attorneys' fee award relative to recovery of the Class overlooks the significant work put into this case by Class counsel before the Supreme Court decided *Mensing*. Substantial fact and expert discovery had already been conducted and copious amounts of briefing on complex legal issues had already been submitted. That work—which convinced this Court that Plaintiffs' claims could not be dismissed at an early stage of the litigation—did not

disappear when the Supreme Court stepped in. Class counsel deserve to be reasonably compensated for that work. If the only factor relevant to the amount of attorneys' fees awarded was the monetary recovery of the Class, attorneys would be less inclined to risk bringing necessary litigation that might not result in a big payday for individual Class members. Finally, Class counsel recognize that the strength of their case was undercut by *Mensing* and lowered their fee request as a result of the limited success achieved. The number submitted is reasonable, and the Court sees no reason to further cut the fee request.

The Court does not discount the judgment of former Magistrate Judge Welsh that both parties made the best deal given the strengths and weaknesses of their case. Though Defendants agreed not to object to a request of attorneys' fees, costs, and incentive awards less than or equal to $4.5 million dollars, it does not follow that Defendants would have willingly paid $4.5 million to Class members. Furthermore, a $4.5 million pot spread among potentially over two million people is not a significant award per person. The objection that any money should have gone not to the lawyers but to the individual Class members is not persuasive upon closer examination.

Generally, a court should cross-check its results using the alternate method for calculating attorneys' fees. *See Gen. Motors*, 55 F.3d at 821 & n.40 (noting that it would be advantageous for court to use "the alternative method to double check the fee . . . the percentage of recovery method can be used to assure that counsel's fee does not dwarf class recovery"). Here, however, such a cross-check serves no purpose. *See Reibstein*, 761 F. Supp. 2d at 260-61 (noting limited utility in cross-checking when total class recovery was relatively small). Placing a value on the relief recovered in the settlement would be pure conjecture. Clearly, the individual Class members receive no money and the injunctive relief obtained evades a fixed number. Nonetheless, some of the factors used to

consider the reasonableness of an attorneys' fee award in common fund cases apply here. The factors, which are not exhaustive, include: (1) the size of the fund created and the number of persons benefitted; (2) the presence or absence of substantial objections by members of the class to the settlement terms and/or the fees requested by counsel; (3) the skill and efficiency of the attorneys involved; (4) the complexity and duration of the litigation; (5) the risk of nonpayment; (6) the amount of time devoted to the case by plaintiffs' counsel; (7) the awards in similar cases; (8) the value of benefits attributable to the efforts of class counsel relative to the efforts of other groups, such as government agencies conducting investigations; (9) the percentage that would have been negotiated had the case been subject to a private contingent fee arrangement at the time counsel was retained; and (10) any innovative terms of settlement. *In re Diet Drugs Prod. Liab. Litig.*, 582 F.3d 524, 541 (3d Cir. 2009) (citing *Gunter v. Ridgewood Energy Corp.*, 223 F.3d 190, 195 (3d Cir. 2000)); *Prudential*, 148 F.3d at 336-40. Here, the Court concludes that the few objections raised to the settlement weighs in favor of approving the settlement, as does the skill of the attorneys, the complexity and duration of the litigation, and the amount of time devoted to this litigation.

D. Incentive Awards

Incentive awards to class representatives lie within the discretion of the court and may be awarded for the benefit conferred on the class. *See Hall v. Best Buy Co.*, 274 F.R.D. 154, 173 (E.D. Pa. 2011); *In re Plastic Tableware Antitrust Litig.*, Civ. A. No. 94-3564, 1995 WL 723175, at *2 (E.D. Pa. Dec. 4, 1995). Factors courts examine when assessing such awards include the financial, personal, and reputational risks to the representative, his or her involvement in the litigation, and the degree to which he or she benefitted as a class member. *Hall*, 274 F.R.D. at 173; *In re U.S. Biosci. Sec. Litig.*, 155 F.R.D. 116, 121 (E.D. Pa. 1994).

There was an objection to awarding incentive awards to individuals other than Sackler and Richards. (Anderson Objection at 16.) Because these individuals are simply Class members and are not Class representatives, they are not entitled to incentive awards. (*Id*.)

The Court does not agree that those individuals other than Sackler and Richards slated to receive incentive awards are simply Class members on par with the unnamed persons who are members of this Class. Rather, they are currently all lead Plaintiffs in the various actions brought prior to this case finding its way to this Court through the Judicial Panel on Multidistrict Litigation. Fred Harrell and Pamela Ray's case was filed in the Eastern District of North Carolina; Richard Krolikowski's case was filed in the Middle District of Florida, Melissa Latvala's case was brought in the Southern District of Ohio, Andrea Leighty's case was brought in the Western District of Washington, Andrew Morgan's case was brought in the Eastern District of Louisiana, and Stephen Rosenfeld's case was brought here in the Eastern District of Pennsylvania. These seven individuals are listed in the settlement agreement as "Parties to this Agreement individually." (Settlement Agreement ¶ 2a.)

Those receiving incentive awards were deposed and answered extensive document requests and interrogatories, often on personal topics involving their mental health. (Kanner Fees Decl. ¶ 9.) Furthermore, this litigation involved a sensitive subject. Plaintiffs understandably would be hesitant to discuss their mental health, particularly in a case likely to receive press coverage. According to Class counsel, "[t]hese individuals were . . . subjected to lengthy depositions during which Defendants aggressively questioned plaintiffs about the nature of their depression, its effect on their lives, and other traumatic life events and tragedies." (*Id*. ¶ 33.) Additionally, these individuals had their medical and pharmacy records subpoenaed. (*Id*.) Of course, these intrusions into one's personal

life are to be expected by individuals seeking to vindicate their rights. However, the Courts finds awards of $10,000 for Sackler and Richards and awards of $5,000 for the other named Plaintiffs a fair trade-off for their sacrifices throughout this litigation.

E. Costs

Class counsel seek costs totaling $1,312,222, broken down as follows: $14,764 in court filing fees; $37,192 in legal research; $49,259 in phone charges, copying, and postage; $86,522 in "Discovery and Legal Services," described as subpoenas, court reporting, videography, database and medical records; $468,647 in travel and lodging; and $655,534 in experts and consultants. (Billing Record Summary.) Class counsel are "entitled to reimbursement of expenses that were adequately documented and reasonably and appropriately incurred in the prosecution of the case." *Moore v. Comcast Corp.*, Civ. A. No. 08-773, 2011 WL 238821, at *5 (E.D. Pa. Jan. 24, 2011). Items such as photocopying, telephone and fax charges, express mail charges, expert witness fees, travel and lodging, and computer-assisted research are necessary for the prosecution of a large class action lawsuit. Accordingly class counsel are entitled to be reimbursed for those costs. *Soon Oh v. AT & T Corp.*, 225 F.R.D. 142, 154 (D.N.J. 2004).

III. CONCLUSION

The Court concludes that the settlement is fair, adequate, and reasonable. The Court also certifies the Settlement Class and awards attorneys' fees, costs, and incentive awards in accordance with the terms of the settlement agreement and this opinion. An Order consistent with this Memorandum will be docketed separately.